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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/686,497 | 10/11/2000 | Richard F Selden | 10278-022001 | 5761 |

26161 7590 05/27/2003

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| EXAMINER |
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NASHED, NASHAAT T

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| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 05/27/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/686,497

Applicant(s)
Selden et al.

Examiner
Nashaat T. Nashed

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 11, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-32 is/are pending in the application.
- 4a) Of the above, claim(s) 16-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 26-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The application has been amended as requested in the communication filed March 11, 2003. Accordingly, claims 1, 3, 4, 8, and 12 have been amended, claims 26-32 have been entered, and claim 15 has been canceled.

Claims 1-14 and 26-32 are under consideration.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. Applicants are required to comply with the sequence rule by filing a new sequence listing, CRF, and an amendment to delete the paper copy of the sequence listing and enter the new one along with a statement indicating that the CRF and the paper copy of the sequence listing are identical and contain no new matter. On page 33, line 3 from the bottom, an amino acid sequence is not identified with a sequence identification number.

In response to the above objection, applicant argue the sequence contains only two arginine residues, and therefore, it is shorter than four amino acid.

Applicants arguments filed 3/11/03 have been fully considered, but they are found unpersuasive. The amino acid sequence in question consists of 5 amino acid, i. e., X-Arg-X-X-Arg wherein X is any amino acid. According to the sequence rules, any sequence disclosed in an application which is longer than four amino acid residues should be identified by a sequence identification number and be listed in the sequence listing in both the paper form and CRF. Applicant must perfect their compliance with sequence rule.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 and 26-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64-135 of copending Application No. 09/407,605 ('605) for the reasons set forth in the prior Office action, paper number 13.

In response to the above rejections, applicants did not traverse the rejection, but indicated that the two applications are commonly owned and they will take an appropriate action upon finding allowable subject matter.

Applicants remarks regarding these rejections filed 3/11/03 are noted, and the rejection will remain on record until further action by the applicants.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seed (IDS (paper number 12): Ref. AG: WO 96/09378) in view of the prior art as exemplified by Kim *et al.* [IDS (paper number 4): Ref AQ: Gene 199, 293-301 (1997)], Morgan *et al.* [Pediatr. Nephrol. (1987) 1, 536-539], Bishop *et al.* (Proc. Natl. Acad. Sci. U. S. A. 83, 4859-4863), and [Nucleic Acid Research 20, 2111-2118 (1992)] for the reasons set forth in the prior Office action, paper number 13.

In response to the above rejections, Applicants argue that a *prima facie* case of obviousness has not been established because the cited references, alone or in combination, fail to provide a teaching or motivation for a skilled in the art to arrive at the presently claimed invention. Also, applicants argue that the prior art teaches away from the claimed invention because Seed caution that "constructing the synthetic genes of the invention it may be desirable to avoid CpG sequences and point to the presumed fact that human sequences are exceedingly CG rich.

Applicants' arguments filed 3/11/03 have been fully considered but they are not deemed to be persuasive. The examiner agrees with the applicants that none of the cited art teach the claimed invention as evidenced by the fact that the rejection is made under 35 U. S. C. 103 and not under 35 U. S. C. 102. In contrast, the examiner disagrees with the applicants allegation that a *prima facie* case of obviousness has not been established. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Seed clearly outlined the claimed inventions and motivates one of ordinary skill in the art change the non-preferred codones in a gene to a preferred codon in order to increase the expression of a desired gene, but he does not describe the application of his invention specifically to an α -galactosidase. Although Seed caution of the increased use of CpG, he did not considered it fatal in reengineering any gene. Also, applicants cite the last sentence of the last paragraph on page 299 of Kim *et al.* which advises the decrease in the number of GC content of a gene. Kim *et al.* states (See Kim *et al.*, the last paragraph on page 299):

"Reengineering the coding sequence to match to the codons frequently found in human genes is beneficial to achieve high-level of expression. Recent reports clearly support this. Altering the coding sequence of the HIV envelope glycoprotein gp120 and jellyfish green fluorescent protein gene to human prevalent codons results in substantial increase in expression efficiency (Haas *et al.* 1996; and Zolotukhin *et al.* 1996."

Based on Kim *et al.* conclusion and Seed teaching, one of ordinary skill in the art would have come to the conclusion that changing the non-preferred codons with preferred human codons would increase the expression of a gene in human cells and that the increasing of the CG content is not fatal. Thus, the ordinary skill in the art would have had the motivation, the skills, and the expectation of success to make and use the claimed invention at the time the invention was made. Applicants should be reminded that common codones in a species are identified based on their occurrence in known genes, and that the human species has not vanished because of its preference for codones having the CG pairs. Claims 26-32 are included because they are drawn to the same subject matter.

Claims directed to a specific nucleic acid sequences optimized for expression in human cells would overcome the rejection under 35 U. S. C. 103 discussed above.

No claim is allowed.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Nashaat T. Nashed, Ph. D.
Primary Examiner